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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,126	01/12/2001	Kazuhiro Tsujita	Q61243	8903

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EXAMINER	
ROZANSKI, MICHAEL T	

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/758,126	TSUJITA ET AL.	
	Examiner	Art Unit	
	Michael Rozanski	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 33-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 33-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/07 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 48-57 are drawn to abnormal area having a higher intensity through the entire wavelength region, throughout part of the wavelength region, for wavelengths greater than 480 nm, for wavelengths below 430 nm, or for wavelengths above 640 nm. These limitations are not supported by the

specification. The Applicant states that the "greater than 480" limitation allegedly described in claims 52 and 53 is disclosed in paragraph [0008]. Examiner finds this passage to disclose "in the vicinity of 480 nm," which is not necessarily greater than 480. Applicant cites paragraph [0190] as support for the claimed "below 430 nm" of claims 54 and 55. Examiner finds this passage to require a specific region of "430 nm to 530 nm," which is clearly not below 430 nm. Applicant cites paragraph [0176] as support for "greater than 640 nm." However, Examiner does not find any reference to 640 nm in this passage.

Claim Objections

Claims 1-15 and 33-57 are objected to because of the following informalities: In regard to claims 1-15 and 33-57, the amended "tissue state image" is not found in the specification nor is it consistent with the dependent claims. It appears as though the term should read "tissue condition image," making it consistent with the rest of the claim language. All depending claims should also reflect this change, including claims 33-57 which were not previously amended to recite the tissue state image.

In regard to claims 6-8 and 11-15, the claims should be dependent upon only one claim as opposed to claims 2, 3, 4, or 5 (as in claims 6-8) or claims 2, 3, 4, 5, 9, or 10 (as in claims 11-15). Further, Applicant must ensure that there is proper antecedence in the claims from which they depend.

In regard to claims 39-42, it is unclear that the comparison of light is in regard to the "judgment" recited in the independent claim. Examiner suggests inserting "making a judgment" after the term "wherein" in each claim.

Claims 39 and 40 are improper because they are drawn to an apparatus, but are dependent upon a method claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 and 33-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palcic et al. '190 (US 5,827,190) in view of Richards-Kortum et al (US 5,421,337).

Palcic et al. teach normalization of at least one fluorescence image by using a remittance image or as otherwise stated, reflected reference light image, in order to correct for many factors including light intensity allowing for differentiation of normal and diseased tissue (col. 2, line 20-col. 3, line 37). Palcic et al. teaches the use of a remittance image to account for non-uniformity due to different changes including illumination intensity (col. 2, lines 28-31).

While Palcic et al. do not specifically address specified values, it would have been obvious to one skilled in the art at the time that the invention was made that the normalization process necessarily incorporates specified values or thresholds in order to differentiate normal from abnormal tissue as this is well within the knowledge of skilled artisans.

With respect to claims 33-43, necessarily the detected values of fluorescence will be above or below the remittance value depending on whether the tissue is normal or abnormal.

Palcic substantially discloses all features of the current invention, but does not teach that diseased tissue intensity is greater than that of normal tissue. Richards-Kortum teaches that the intensity of normal gastrointestinal (GI) tissue is greater than diseased GI tissue in the 400-420 nm range, but lower in the 430-480 nm range (col. 11, lines 3-10; col. 12, line 64-col. 13, line 15). Thus fluorescence endoscopic imaging as described by Palcic could be used in the GI tract, where the spectral response (flourescence intensity) of diseased tissue is greater than the normal tissue intensity from 430-480 nm. Further, the process of integrating the fluorescence intensity (Palcic - col 2, line 24) could be performed with the spectral data (obtained by the method taught by RIchards-Kortum) from the 430-480 nm dataset. Therefore, the teachings of Richards-Kortum do not teach away from the teachings of Palcic because Richards-Kortum teaches of a tissue type and a spectral response that could be used in the integration process of Palcic. It would have been obvious to the skilled artisan to modify Palcic, to obtain the spectral response of GI tissue with fluorescence endoscopy

wherein diseased tissue intensity is greater than normal in the 430-480 nm range as taught by Richards-Kortum, because it is commonly known that endoscopes can be used to obtain images of different internal parts of the body including the GI tract.

With respect to claim 33 and claims 44-47, Palcic et al. also do not specifically mention chrominance or luminance signal components with respect to the fluorescence image and reflected reference light or judgment means based on a ratio. However, Richards-Kortum et al. make reference to correlation features of fluorescence spectra to tissue type in a quantitative way using ratios of fluorescence intensities at various wavelengths from the fluorescent image and reflected reference light (col. 9, lines 10-34). In addition, color (chrominance) and intensity (luminance) components of autofluorescence are recorded for analysis (col. 21, lines 15-55). It would have been obvious to one with ordinary skill in the art at the time the invention was made to improve the diagnosis of tissues through a better display of fluorescence images.

Response to Arguments

Objection to claims 39-43 as reciting the response of tissue to excitation light is withdrawn. The 101 rejection that was also made due to non-statutory subject matter is also withdrawn. However, claims 39-42 are now objected to because it is unclear that the comparison of light is in regard to the "judgment" recited in the independent claim. Examiner suggests inserting “making a judgment” after the term “wherein” in each claim. Please note objections regarding claims 1-15 and 33-57 as well.

In regard to Applicant's assertion that no new matter has been added in claims 48-57, the Examiner does not find this persuasive. For example, Applicant states that the "greater than 480" limitation of claims 52 and 53 are disclosed in paragraph [0008]. Examiner finds this passage to disclose "in the vicinity of 480 nm," which is not necessarily greater than 480. Applicant cites paragraph [0190] as support for the claimed "below 430 nm" of claims 54 and 55. Examiner finds this passage to require a specific region of "430 nm to 530 nm," which is clearly not below 430 nm. Applicant cites paragraph [0176] as support for "greater than 640 nm." However, Examiner does not find any reference to 640 nm in this passage. Please see the newly added 112 rejection.

In regard to the 103 art rejection, Applicant asserts that it is not obvious to combine the references. Specifically, Applicant states that because Richards-Kortum discloses both higher and lower intensities for adenomas and Palcic discloses only lower intensities for diseased tissues Palcic teaches away from the teachings of Richards-Kortum. However, Examiner maintains that the references would be obvious to combine. Palcic discloses the use of fluorescence endoscopy to image bronchial, larynx, and nasopharynx tissue, whereby the spectral response shows that normal tissue has a greater intensity than the diseased tissue (see Figures 1B-1D). Endoscopic imaging is commonly used to obtain images not only of the aforementioned tissues, but also of gastrointestinal tissue. Palcic substantially discloses all features of the current invention, but does not teach that diseased tissue intensity is greater than that of normal tissue. Richards-Kortum teaches that the intensity of normal

gastrointestinal (GI) tissue is greater than diseased GI tissue in the 400-420 nm range, but lower in the 430-480 nm range. Thus fluorescence endoscopic imaging as described by Palcic could be used in the GI tract, where the spectral response (flourescence intensity) of diseased tissue is greater than the normal tissue intensity from 430-480 nm. Further, the process of integrating the fluorescence intensity could be performed with the spectral data (obtained by the method taught by RIchards-Kortum) from the 430-480 nm dataset. Therefore, the teachings of Richards-Kortum do not teach away from the teachings of Palcic because Richards-Kortum teaches of a tissue type and a spectral response that could be used in the integration process of Palcic. It would have been obvious to the skilled artisan to modify Palcic, to obtain the spectral response of GI tissue with fluorescence endoscopy wherein diseased tissue intensity is greater than normal in the 430-480 nm range as taught by Richards-Kortum, because it is commonly known that endoscopes can be used to obtain images of different internal parts of the body including the GI tract.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MR

ERIC F. WINAKUR
PRIMARY EXAMINER